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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,676	07/16/2001	Zheng Xin Dong	00537-187002	2104

7590 02/09/2005

Biomeasure Incorporated
27 Maple Street
Milford, MA 01757

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,676	DONG ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III DETAILED ACTION

Claims 1-12 are currently pending.

Restriction Requirement

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional examination fees must be paid.

I. Claims 1-9, drawn to peptides, classified in class 530, subclass 324, and their pharmaceutical composition classified in class 514, subclass 12.

II. Claim 10, drawn to eliciting an agonist effect from a GLP-1 receptor, classified in class 514, subclass 12.

III. Claims 11,12 drawn to method of treating various diseases using product of Group I, classified in class 514, subclass 12.

Group III is further divided into following Groups:

III.1. Claims 11,12 , drawn to method of treating diabetes.

III.2. Claim 11, drawn to method of treating obesity.

III.3. Claim 11, drawn to method of treating glucagonomas.

III.4. Claim11, drawn to method of treating airways secretory disorders.

III.5. Claim 11, drawn to method of treating metabolic disorder.

III.6. Claim 11, drawn to method of treating arthritis.

III.7. Claim 11, drawn to method of treating osteoporosis.

III.8. Claim 11, drawn to method of treating nervous system disease.

III.9. Claim 11, drawn to method of treating restenosis.

III.10. Claim 11, drawn to method of treating neurodegenerative disease.

III.11. Claim 11, drawn to method of treating renal failure.

III.12. Claim 11, drawn to method of treating congestive heart failure.

III.13. Claim 11, drawn to method of treating nephrotic syndrome.

III.14. Claim 11, drawn to method of treating cirrhosis.

III.15. Claim 11, drawn to method of treating pulmonary edema.

III.16. Claim 11, drawn to method of treating hypertension.

The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I to III. Group II is not the contribution over the prior art because it is described or suggested by references teaching GLP-1 derivatives encompassed by the instant claims; see, for example, Buckley et al. (US Patent 5,545,618) teaching homologous derivatives. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

Inventions I and II, III are related as product and processes of use. Methods II, III.1-III.16 are alternate methods of using the compound of Group I; the product as claimed can be used in a materially different processes such as peptide synthesis; the methods of use can be practiced with a broad variety of drugs beyond the claimed peptides.

Inventions II and III are related as different methods which are not connected in design, operation or effect. The methods have different functions and different effects, and a reference teaching treatment of e.g., heart failure, will not necessarily teach eliciting agonist effect from GLP receptors.

The methods of use III.1-III.16 are drawn to methods of treatment of 16 distinct disorder conditions which are patentably distinct because the disorder conditions are not related to each other, have different mechanisms of

development and etiology, and the methods of treatment have different enablement requirements. The groups require different literature search and a reference teaching treatment of one disorder (e.g., secretory disorder of airway) will not teach treatment of any other disorder (e.g., diabetes or osteoporosis).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and the patent and/or literature search required for different groups is different, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a)).

This application contains claims directed to more than one species of the generic invention. The species identified below are deemed to lack Unity of Invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1.

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

The claims of Groups are generic to a plurality of disclose patentably distinct species of peptides, which encompass a plethora of different compound species that require a burdensome classification, and/or bibliographic, manual and computer search. Accordingly, regardless of which group is elected, Applicant is required

under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound), even though the requirement is traversed. A choice of subgenus species is not responsive. Please make an election of species from those listed as species in the claims.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb